DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

#15

APR 15 1988

Re: Novantrone
Docket No. 88E-0132

The Honorable Donald J. Quigg
Assistant Secretary and Commissioner
of Patents and Trademarks
Washington, DC 20231

Dear Commissioner Quigg:

This is in regard to the application for patent term extension for U.S. Patent No. 4,197,249 filed by American Cyanamid Company under 35 U.S.C. 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Novantrone (mitoxantrone hydrochloride), the human drug product claimed by U.S. Patent No. 4,197,249.

The total length of the review period for Novantrone is 3,145 days. Of this time, 1,836 days occurred during the testing phase, and 1,309 days occurred during the approval phase. The periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: May 16, 1979.

   The applicant claims April 16, 1979 as the date the investigational new drug application (IND) for Novantrone became effective. However, FDA records indicate that the IND became effective on May 16, 1979.

2. The date the application was initially submitted with respect to the human drug product under subsection 505(b) of the Federal Food, Drug, and Cosmetic Act: May 24, 1984.

   The applicant claims that a new drug application for Novantrone (NDA 19-297) was initially submitted on May 18, 1984. However, FDA did not receive the application until May 24, 1984.

3. The date the application was approved: December 23, 1987.

   FDA has verified the applicant's claim that NDA 19-297 was approved on December 23, 1987.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Alphonse R. Noe, Manager
Patent Law Department
American Cyanamid Company
1937 West Main Street
P.O. Box 60
Stamford, CT 06904-0060